

REMARKS

The Office requires restriction of the claims to one of the following:

Group I, claims 1 and 2, drawn to a computer system comprising at least one database correlating with presence of at least one mutation in a HIV protease and a change in susceptibility of at least one strain of HIV to a protease inhibitor comprising at least one record corresponding to a correlation between at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E in said protease, and treatment with at least a protease inhibitor;

Group II, claims 3, 4, 9 and 10, drawn to a method for evaluating the effectiveness of a protease inhibitor as an antiviral therapy for a patient infected with at least one mutant HIV strain or for evaluating a change in viral drug susceptibility, comprising:

- (i) collecting a sample from an HIV-infected patient;
- (ii) determining whether the sample comprises a nucleic acid encoding HIV protease having at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E;
- (iii) correlating the presence of said at least one mutation of step (ii) to a change in effectiveness of said protease inhibitor or in viral drug susceptibility.

Group III, claims 5 and 6, drawn to a method for evaluating a drug effective against mutant HIV protease, comprising:

- (i) providing a nucleic acid comprising mutant HIV protease comprising at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E;
- (ii) recombining said nucleic acid comprising mutant HIV protease of step (i) into a pro-viral nucleic acid deleted for said sequence to generate a recombinant HIV virus;
- (iii) determining a phenotypic response to said drug for said HIV recombinant virus; and
- (iv) identifying a drug effective against mutant HIV based on the phenotypic response of step (iii).

Group IV, claims 7, 8, 13 and 14, drawn to a method of identifying a drug effective against mutant HIV protease, comprising:

- (i) providing a HIV protease comprising at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E;
- (ii) determining the activity of said drug on said HIV protease;
- (iii) determining the activity of said drug on wild type HIV protease;
- (iv) determining the ratio of the activity determined in step (iii) over the activity determined in step (ii);
- (v) identifying an effective drug against mutant HIV based on the ratio of step (iv).

Group V, claims 11 and 12, drawn to a method for evaluating a change in viral drug susceptibility, comprising:

- (i) providing an HIV comprising a protease comprising at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E;
- (ii) determining a phenotypic response of said virus to said drug; and
- (iii) correlating the phenotypic response of step (ii) to a change in viral drug susceptibility.

Group VI, claims 15 and 16, drawn to a vector for performing phenotypic analysis comprising an HIV sequence having at least one mutation in the HIV protease gene chosen from 41S, 41T, 41I, 41K, 41G and 70E.

Group VII, claims 17 and 18, drawn to an isolated and purified HIV protease sequence having at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E, wherein said at least one mutation in said sequence correlates to a fold change in susceptibility towards a HIV protease inhibitor.

Group VIII, claims 19 and 20, drawn to an isolated and purified oligonucleotide comprising a HIV protease sequence of 5 to 100 bases for in vitro diagnosis of viral drug resistance, characterized in that said oligonucleotide comprises at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E.

In response, Applicants elect Group II, claims 3, 4, 9 and 10 without traverse.

The Office also requires election of one mutation of HIV protease. In response, Applicants elect mutation 4T. This election is made with traverse. Applicants

respectfully submit that the claimed mutant HIV strains all share common features, including that they all are a point mutation of HIV and that they all correlate to a fold change in susceptibility or resistance of an HIV viral strain towards at least one protease drug. See the specification at, for example, page 3, lines 27-31.

Early consideration and prompt allowance of the pending claims are respectfully requested. If the Office requires any information, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

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